

hours before or after taking any other drugs.”

(ii) “Stop use and ask a doctor if [bullet] symptoms get worse [bullet] diarrhea lasts more than 2 days”.

(d) *Directions.* The labeling of the product contains the following information under the heading “Directions”:

(1) *For products containing any ingredient identified in § 335.10.* The labeling states “[bullet] drink plenty of clear fluids to help prevent dehydration caused by diarrhea”.

(2) *For products containing bismuth subsalicylate identified in § 335.10(a).* The labeling states “[bullet] adults and children 12 years and over:” 525 milligrams “every 1/2 to 1 hour, or” 1,050 milligrams “every hour as needed [bullet] do not exceed” 4,200 milligrams “in 24 hours [bullet] use until diarrhea stops but not more than 2 days [bullet] children under 12 years: ask a doctor”.

(3) *For products containing kaolin identified in § 335.10(b).* The labeling states “[bullet] adults and children 12 years and over:” 26.2 grams “after each loose stool [bullet] continue to take every 6 hours until stool is firm but not more than 2 days [bullet] do not exceed” [262 grams] “in 24 hours [bullet] children under 12 years of age: ask a doctor”.

(e) *Products that meet the criteria established in § 201.66(d)(10) of this chapter.* The information described in § 201.66(c) of this chapter shall be printed in accordance with the following specifications.

(1) The labeling shall meet the requirements of § 201.66(c) of this chapter except that the information in § 201.66(c)(3) of this chapter may be omitted, and the information in § 201.66(c)(5) and (c)(6) of this chapter may be presented as follows:

(i) The words “Contains salicylate,” may be omitted from the warning in § 335.50(c)(2)(i)(B).

(ii) The subheading “When using this product” in § 335.50(c)(2)(iv) may be omitted.

(iii) The words “continue to” may be omitted from the directions in § 335.50(d)(3).

(2) The labeling shall be printed in accordance with the requirements of § 201.66(d) of this chapter except that any requirements related to

§ 201.66(c)(3) of this chapter and the bullet in the warning in § 335.50(c)(1)(i) may be omitted.

[68 FR 18881, April 17, 2003, as amended at 69 FR 26302, May 12, 2004]

PART 336—ANTIEMETIC DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Sec.

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336.3 Definition.

Subpart B—Active Ingredients

336.10 Antiemetic active ingredients.

Subpart C—Labeling

336.50 Labeling of antiemetic drug products.

336.80 Professional labeling.

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 52 FR 15892, Apr. 30, 1987, unless otherwise noted.

Subpart A—General Provisions

§ 336.1 Scope.

(a) An over-the-counter antiemetic drug product in a form suitable for oral administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this part and each of the general conditions established in § 330.1.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 336.3 Definition.

As used in this part:

Antiemetic. An agent that prevents or treats nausea and vomiting.

Subpart B—Active Ingredients

§ 336.10 Antiemetic active ingredients.

The active ingredient of the product consists of any of the following when used within the dosage limits established for each ingredient in § 336.50(d):

(a) Cyclizine hydrochloride.

(b) Dimenhydrinate.

(c) Diphenhydramine hydrochloride.